REMARKS

I. Amendment

According to the Advisory Action, the previously presented claim amendments have not yet been entered. Accordingly, the same claim amendments are repeated herein.

By this amendment, claims 1 and 2 have been amended and claims 3 and 4 have been cancelled.

This amendment adds no new matter to the specification. Support for the amendment to claim 1 may be found at page 23, line 31 – page 24, line 29 *inter alia*.

II. Discussion of the Objection to the Declaration

The Examiner has objected to the Declaration for allegedly misspelling the name of one of the inventors. However, Applicants do not believe that the Declaration is defective. Apparently when Dr. Namba's name is translated from Japanese to English, both the spellings of Nanba and Namba may be used.

Applicants believe that the rule which applies to this situation is under Sec. 605.04(b) of the MPEP. Therein, it is stated that a new Declaration is not necessary for typographical or transliteration errors in the spelling of an inventor's name. The interchange of the letters "n" and "m" may be considered to be a transliteration of the foreign name, though not an error.

Therefore Applicants respectfully request withdrawal of the objection to the Declaration.

III. Discussion of the Objection to Claims 3 and 4

Claims 3 and 4 have been objected to for not properly indicating the status of the claims. By this amendment, claims 3 and 4 have been cancelled, and their status has properly been indicated.

Therefore Applicants respectfully request withdrawal of the objection to claims 3 and 4.

IV. Discussion of the Rejection under 35 U.S.C. Sec. 112, First Paragraph

Claims 1- 4 have been rejected under 35 U.S.C. Sec. 112, first paragraph for allegedly failing to comply with the written description requirement.

The Examiner has objected to the phrase "wherein said cell is expressing at least three endogenous cytochrome P450 CYP genes" in claim 1 as allegedly non-compliant with the written description requirement. By this amendment, the phrase has been deleted, rendering the rejection moot.

Moreover, by this amendment Applicants have amended claim 1 to recite the enzymes as CYP1A1, CYP1A2 and CYP3A. Applicants believe that support for this amendment may be found in the Examples section of the specification as originally filed, namely in Example 3. For the Examiner's convenience, Applicants note that the recited OUMS-29 culture of Example 3 is the same as the deposited material FERM BP-6328. This information is provided in the specification at page 21, lines 11-19. Applicants submit that the aspect of their invention set forth in claim 1 as amended is adequately enabled.

Claim 2 has been amended to reflect the activities tested in Example 2, on pages 22 and 23. Applicants therefore assert that there is adequate support for claim 2 as amended.

By this amendment, claims 3 and 4 have been cancelled.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection.

V. Discussion of the Rejection under 35 U.S.C. Sec. 112, Second Paragraph

Claims 1-5 have been rejected under 35 U.S.C. Sec. 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim subject matter which Applicants regard as the invention.

The Examiner has objected to the phrase "wherein said cell is expressing at least three endogenous cytochrome P450 CYP genes" in claim 1 as allegedly indefinite. By this amendment, the phrase has been deleted, rendering the rejection moot.

Claims 3 and 4 have been cancelled, and claims 2 and 5 depend from claim 1. Applicants submit that the more specific dependent claim is also definite.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, second paragraph rejection.

VI. Discussion of a Previous Provisional Double-Patenting Rejection

In the Office Action dated June 2, 2003, a provisional double patenting rejection was made in view of U.S. Patent Application Serial No. 10/009,158. Applicants requested that the rejection be held in abeyance.

Applicants would now like to inform the Examiner that U.S. Patent Application Serial No. 10/009,158 has matured into U.S. Patent No. 6,756,229. Applicants respectfully request the Examiner's consideration of the recently-issued patent.

Moreover, the cited patent recites isolated and transformed cell lines derived from human hepatocarcinoma cells, while the present invention is directed to immortalized hepatocyte cell culture of human normal cell origin as set forth in claim 1 as amended. Since hepatic carcinoma cells and normal hepatocytes are functionally different, Applicants do not believe that there are any double patenting issues.

VII. Discussion of the Objection to the Abstract

In the Advisory Action, the Examiner made a new objection to the Abstract, for containing legal phraseology.

By this amendment, the word "said" has been removed from the Abstract. The Abstract has also been shortened, in accordance with U.S. Patent and Trademark Office Requirements.

Therefore Applicants respectfully request withdrawal of the objection to the Abstract.

VIII. Acceptability of the Drawings

Applicants hereby acknowledge the acceptability of the formal drawings as indicated in the Advisory Action.

IX. Discussion of Deposit Requirements

In the Advisory Action, the Examiner indicated that a Declaration as to the Deposit was required. The requested statement accompanies this response.

X. Additional Comments on the Advisory Action

As a continuation of point 2, the Examiner stated that the amendment mailed September 1, 2004 could not be entered because it would require further search and consideration. The Applicants do not understand the basis for this conclusion.

Specifically, the Examiner stated that "the amendment does not require the cell to express the enzymes CYP1A1, CYP1A2 and CYP3A". However, the previous amendment to claim 1 (repeated in the present amendment) changes the amendment to specify enzymes. The enzymes were recited in claim 4 as originally filed. Moreover, should the term "or" be the reason for the Examiner's statement, Applicants note that the claim as originally filed contained the term "or" on line 3. For these reasons, Applicants do not believe that their previous amendment raised any new issues which would require further search.

XI. Conclusion

Reconsideration of the claims is requested. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

Dated: September 29, 2004

Elaine M Ramesh

(847) 383-3391
(847) 383-3372

Elaine M. Ramesh, Ph.D., Reg. No. 43,032
Mark Chao, Ph.D., Reg. No. 37,293
Attorney for Applicants
Customer No. 23115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA

Certificate of Mailing under 37 CFR 1.10

The undersigned hereby certifies that this document, along with any attachments, is being deposited in an envelope addressed to The Commissioner of Patents and Trademarks, with sufficient postage with the United States Postal Service EXPRESS MAIL Post Office to Addressee Service on this date September 29, 2004 .

Express Mail Label No. EV 524905985 US

Gail L. Winokur

Printed Name: Gail L. Winokur

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	09/673,958	Art Unit:	1635
Filed:	August 13, 2001	Examiner:	B. Whiteman
1st Inventor:	M. Nanba	Allowed:	
For:	A Human Derived Immortalized Liver Cell Line	Batch:	
Atty. Dkt. No.	2519 US0P	Paper No.:	

DECLARATION AS TO THE DEPOSIT OF A MICROORGANISM

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I hereby declare:

1. that I, Elaine M. Ramesh, am an attorney of record in the above-mentioned pending U.S. Patent Application Serial No. 09/673,958, entitled "Human Derived Immortalized Liver Cell Line", which was filed on August 13, 2001 in the United States Patent and Trademark Office;

2. that cultures of strain OUMS-29 have been deposited according to the Budapest Treaty at the National Institute of Bioscience and Human-Technology (NIBH), Agency of Industrial Science and Technology, Ministry of International Trade and Industry, 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken 305-8566, Japan;

3. that the deposits meet the criteria set forth in 37 C.F.R. Sections 1.801-1.809, which deposit OUMS-29 is designated as deposit FERM BP-6328;

4. that the cultures will be available during the pendancy of the above-identified patent application to one determined by the Commissioner of Patents and Trademarks to be entitled thereto under 37 C.F.R. Sec. 1.14 and 35 U.S.C. Sec. 122;

5. that upon issuance of a patent on the above-identified application, all restrictions as to public availability of the culture deposit will be irrevocably removed and that said culture deposits will be replaced should the depository be unable to distribute the sample upon a proper request, during the period that extends thirty years from the date of the deposit, or the period of the enforceable life of the patent, or the period of five years after the last public request for the deposit, whichever period is longest, with the understanding that the availability of a deposit does not constitute a license to practice the subject invention in derogation of patent rights granted by governmental action; and,

6. that I declare further that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements so made are punishable by fine or imprisonment, or both under Sec. 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the present patent specification or any patent issuing thereon.

9/29/04

Date

Elaine M Ramesh

(847) 383-3391
(847) 383-3372

Elaine M. Ramesh, Ph.D., Reg. No. 43,032
Mark Chao, Ph.D., Reg. No. 37,293
Attorney for Applicants
Customer No. 23,115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA